



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service *9507 18*

Food and Drug Administration
5100 Paint Branch Pkwy, HFS-607
College Park, Maryland 20740

OCT 22 2004

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Mr. Joseph Harris
c/o Getbuf.com
7710 Huron Dr.
Gainesville, VA 20155

Dear Mr. Harris:

The Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.getbuf.com> and has concluded that claims on this web site cause your product "IDS Carb Shuttle" to be misbranded under the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet home page: <http://www.fda.gov>.

Under section 403(r)(6) of the Act, dietary supplement labeling may include claims about the supplement's effect on the structure or function of the human body (structure/function claims), provided that certain requirements are met. [21 U.S.C. § 343(r)(6)(A).] One of these requirements is that the manufacturer of a dietary supplement bearing a "structure/function" claim must have substantiation that the claim is truthful and not misleading. [21 U.S.C. § 343(r)(6)(B).]

The labeling of IDS Carb Shuttle bears structure/function claims, including the following:

- "Shuttle Carbs Into Muscles Instead Of Fat Using Natural R-ALA!"
- "Carb Shuttle™ retrains your body to react to sugars...[s]ending carbohydrates to muscles for immediate energy, not depositing it as fat!"
- "Carb Shuttle™ has the unique ability to heighten the sensitivity of receptors in your body that are actually responsible for where sugars are stored; Carb Shuttle™ really dictates how much fat your body creates from carbohydrates!"

We have reviewed these claims and have concluded they are not supported by competent and reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your product to be misbranded within the meaning of sections 403(a)(1) and 403(r)(6)(B) of the Act. [21 U.S.C. § 343(a)(1), (r)(6)(B).] It is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is misbranded. [21 U.S.C. § 331(a).] It is a violation of section 301(k) of the Act to commit any act with respect to a food if such act is done while

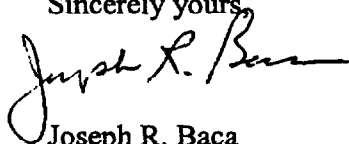
such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being misbranded. [21 U.S.C. § 331(k).]

This letter is not an all-inclusive review of your web site and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. You should take prompt action to correct any violations, including the violations identified in this letter. Failure to do so may result in enforcement action, including seizure or injunction, without further notice.

If you have scientific evidence which you believe substantiates that your claims for IDS Carb Shuttle are truthful and not misleading, please provide it to us within fifteen (15) working days of receipt of this letter. Alternatively, please advise this office, in writing and within fifteen working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to ensure that similar violations do not occur in the future. If corrective action cannot be completed with fifteen working days, state the reason for the delay and the time within which the corrections will be made.

Your reply should be sent to the attention of Compliance Officer Quyen Tien at the above address.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Joseph R. Baca", written over the typed name.

Joseph R. Baca

Director

Office of Compliance

Center for Food Safety and Applied Nutrition